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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,602	11/16/2000	David William Holden	RPMS 101 CON(3)	4552

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/714,602

Applicant(s)

HOLDEN, DAVID WILLIAM

Examiner

Gerald Leffers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 57-79, 86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 57-79, 86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 3 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9, 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 3, 57-79 and 86 in Paper No. 10 is acknowledged. Nonelected claims 80-85 were cancelled in Paper No. 10. Claims 3, 57-79 and 86 are pending in this application.

Information Disclosure Statement

Receipt is acknowledged of information disclosure statements filed 6/18/01 (Paper No. 3), 6/18/02 (Paper No. 9) and 9/11/02 (Paper No. 11). It is noted that Paper No. 9 is a duplicate of Paper No. 3 that was requested by the examiner because many of the references listed in the IDS of Paper No. 3 were not available. Accordingly, only the PTO Forms for Paper No. 9 and Paper No. 11 have been mailed with this action. For Paper No. 9, only those references that were actually provided in the submission of Paper No. 9 have been considered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Copies of the claims for the issued patents of the following rejections have been attached to this office action.

Claims 3, 57-79 and 86 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-6, 8-9, 12-22, 24-31 of U.S. Patent No. 5,876,931. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The instant application is a continuing application of the application that issued as the '931 patent. The claims of the '931 patent are directed towards an insertional inactivation-based method for identifying a pathogenic microorganism having a reduced adaptation to a particular environment. Each mutant within the population of mutants used in the methods comprises a unique marker sequence so that reference to a control population of cells that comprise the same combination of mutations/marker sequences can readily identify the mutants that do not do well in a particular environment (e.g. in a multicellular organism).

The instant claims are directed towards similar methods that embrace any type of method for generating the population of mutants that are screened. As before, the mutants within the population of mutants screened each have a unique marker sequence. Thus, the instant claims are broader genus claims that encompass the species claims of the '931 patent. The species claims of the '931 patent necessarily make obvious the broader claims of the instant patent. Moreover, issuance of the instant claims would

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improperly result in the possibility of harassment by multiple assignees having rights to the invention claimed in the '931 patent.

Claims 3, 57-79 and 86 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-21, 25-26 of U.S. Patent No. 6,015,669. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The instant application is a continuing application of 08/637,759, which was the 371 National Stage application of PCT/GB95/02875. The '669 patent is a continuation of PCT/GB95/02875. The claims of the '669 patent are directed towards an insertional inactivation-based method for identifying a microorganism having a reduced adaptation to a particular environment. Each mutant within the population of mutants used in the methods comprises a unique marker sequence so that reference to a control population of cells that comprise the same combination of mutations/marker sequences can readily identify the mutants that do not do well in a particular environment (e.g. in a multicellular organism).

The instant claims are directed towards similar methods that embrace any type of method for generating the population of mutants that are screened. As before, the mutants within the population of mutants screened each have a unique marker sequence. Thus, the instant claims are broader genus claims that encompass the species claims of the '669 patent. The species claims of the '669 patent necessarily make obvious the broader claims of the instant patent. Moreover, issuance of the instant claims would

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improperly result in the possibility of harassment by multiple assignees having rights to the invention claimed in the '669 patent.

Claims 3, 57-60, 64-68, 71-72, 74-79 and 86 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 10-15 and 21 of U.S. Patent No. 6,342,215. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The instant application is a continuing application of the application that issued as the '215 patent. The claims of the '215 patent are directed towards mutant microorganisms having a reduced adaptation to a particular environment that are produced by a method of insertional activation of a population of microorganism where each mutant microorganism has a unique marker sequence. These are product-by-process claims that involve a specific methodology for generating mutants (i.e. insertional inactivation of genes).

The claims of the instant application are directed towards a more general method of obtaining microorganisms with a reduced adaptation for a particular environment wherein the method for generating the population of mutant microorganisms is not specified. The instant claims are also directed towards selected microorganisms and the genes, wildtype and mutant, that correlate with reduced adaptation to a particular environment. Thus, the species claims of the '215 patent make obvious the more general claims of the instant application which completely encompass those of the '215

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application. Moreover, issuance of the instant claims would improperly result in possible harassment by multiple assignees having rights to the subject matter of the '215 claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 74 is drawn towards a wildtype gene corresponding to a mutant gene that confers upon a microorganism a reduced adaptation to a particular environment. Claim 75 is drawn towards a microorganism comprising a mutation that confers upon a microorganism a reduced adaptation for a particular environment. Claim 79 is drawn towards a mutant microorganism obtained by the method of claim 57. Claims 74-79 are not necessarily product by process claims. Claim 79 is a product by process claim. However, the process of claim 57 does not impart some characteristic upon the mutant microorganism (e.g. insertional inactivation) that distinguishes the microorganism from the prior art. Thus, any teaching of the prior art of a mutation that results in a reduced adaptability for a microorganism would necessarily read on claims 75 and 79. Once a mutation is identified in a given gene, the investigator would necessarily have possession of the wildtype gene corresponding to the mutant gene (i.e. claim 74).

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Claims 75 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Finlay et al (Molecular Microbiology, 1988, Vol. 2, No. 6, pages 757-766; see the entire reference).

Finlay et al teach the identification and characterization of TnphA mutants of Salmonella (e.g. abstract). According to Finlay et al, at least some of the mutants had a reduced virulence compared to wildtype Salmonella in mice (e.g. the abstract).

Claimed 74-75 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Camilli et al (Journal of Bacteriology, July 1990, Vol. 172, No. 7, pages 3738-3744; see the entire reference).

Camilli et al teach the isolation of a series of mutants of Listeria monocytogenes, including auxotrophic and nonhemolytic insertion mutants (e.g. the Abstract). Such mutants would necessarily have a reduced adaptation to different environments. At least one of the mutants is determined to be within a particular gene (i.e. hylA, the L. monocytogenes hemolysin structural gene).

Conclusion

No claims are allowed.

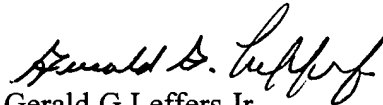
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gerald G Leffers Jr.

Examiner

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ggl
October 1, 2002